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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,271	08/31/2006	Stefan Gallinat	P29848	3145

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
09/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/581,271	GALLINAT ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-44* is/are pending in the application.

4a) Of the above claim(s) *31 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-30, 32-37, 39-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicants request acknowledgment of the foreign priority in the present application. It is hereby noted that this present application claims priority to PCT/EP04/13254 filed on 11/22/2004 which claims priority to GERMANY 103 57 451.4 filed on 12/3/2003.

Applicants argue over the 35 USC 112, second paragraph rejections. Applicants argue that the terminology that was rejected is included in the specification. In response to the arguments, it is noted that the way that the claims read do not by themselves make sense. For example, the phrase in claim 39 "for protecting skin in cases of sensitively determined and dry skin" is not a phrase that makes sense on its own. Perhaps a phrase such as "for protecting skin in cases of sensitive and dry skin" may be more appropriate. Regarding claim 44, the phrase "treating functional disorders of skin appendages" is also not a phrase that makes sense on its own. It is unclear what functional disorders of skin appendages are.

Applicants argue over the 35 USC 112, first paragraph rejection. In particular, Applicants state that the same action is taken in order to prevent any of the conditions set forth as for the treatment. Applicants further argue that there is no evidence provided which would support an allegation of undue experimentation.

It is noted that the rejection does discuss that the state of the art regarding treatment of intrinsic ageing is that the signs of ageing cannot be stopped or slowed down and the only way to prevent extrinsic ageing is protecting skin from the sun,

quitting smoking and eliminating skin exercises; however, prevention does not occur by application of a skin preparation or of a drug as discussed in the rejection. Therefore there would be an undue amount of experimentation to prevent something that the art does not recognize as preventable.

Applicants argue over the 35 USC 103 rejection over Stab (US PgPub 2006/0093633) in view of Max (US PgPub 2005/0158350). Applicants argue that neither reference qualifies as prior art under 102 (a) and (b) and that Stab does not qualify as prior art under 102 (e).

In response to the above arguments, it is noted that the Stab and Max references were not applied under 102 (a) or (b). Both prior art references qualify under 102 (e). As noted in the rejection, the Applicants cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. With that being said, at the present time the priority date of the present application is 11/22/2004. Applicants focus on the published dates of the references; however, the priority date for 102 (e) goes to the filing date of the references. Accordingly, the U.S. effective filing date of the Stab reference is 11/19/2004. In addition, the U.S. effective filing date of the Max reference is 10/18/2004. Therefore, both references qualify as prior art under 102 (e) and the rejection is maintained.

Priority

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections – 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 39 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what "for protecting skin in cases of sensitively determined and dry skin" means. Clarification is required.

Claim 44 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what "functional disorders of skin appendages" is referring to. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-41, 44 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating inflammatory skin conditions, treating symptoms of intrinsic or extrinsic skin aging, treating harmful effects of ultraviolet

radiation on skin, treating pigment disorders of the skin and treating functional disorders of the skin, does not reasonably provide enablement for preventing skin conditions, preventing symptoms of intrinsic or extrinsic skin aging, preventing harmful effects of ultraviolet radiation on skin, preventing pigment disorders of skin or preventing functional disorders of skin appendages. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

1) The nature of the invention and breadth of the claims: The instant claims are drawn to methods of preventing or treating inflammatory skin conditions or for protecting skin in cases of sensitively determined and dry skin, methods of preventing or treating symptoms of intrinsic or extrinsic skin aging and for preventing or treating harmful effects of ultraviolet radiation on skin, methods of preventing or treating pigment

disorders of skin and methods of preventing or treating functional disorders of skin appendages comprising applying the preparation as claimed in claim 20 to the skin.

2) The state of the prior art: The art teaches that signs of intrinsic aging are: fine wrinkles, thin and transparent skin, loss of underlying fat among other things. Extrinsic aging occurs by environmental factors, such as sun exposure. It is taught that the intrinsic aging process cannot be stopped or slowed down and the way to prevent extrinsic skin aging is to protect the skin from the sun, quitting smoking and eliminating facial exercises. It is taught that treatments are available for the visible signs of aging; however, there is no prevention of aging following treatment of a drug. This is one example of a skin condition, such as aging. However, there is no finding in the art that prevention of inflammatory skin conditions, preventing pigment disorders or preventing functional disorders of skin appendages occurs following normal treatment regimens. (http://www.skincarephysicians.com/agingskinnet/basicfacts.html).

3) The amount of guidance or direction presented or the presence or absence of working examples: There is no guidance in the present specification that the composition of the present claim 20 prevents inflammatory skin conditions, prevents symptoms of intrinsic or extrinsic skin aging, prevents pigment disorders or prevents functional disorders of the skin appendages.

4) The quantity of experimentation necessary: "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue

experimentation. In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed Cir. 1993)". Undue experimentation would be required in order to practice Applicant's invention because there are no examples provided in the specification.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-30, 32-37, 39-44 rejected under 35 U.S.C. 103(a) as being unpatentable over Stab et al. (US PgPub 2006/0093633) in view of Max et al. (US PgPub 2005/0158350).

Stab et al. teaches cosmetic and/or dermatological preparations containing one or more 2,3-dibenzylbutyrolactone derivatives, including the elected species of arctiin (paragraphs 0001, 0036). Stab et al. teach that it is easy to incorporate the 2,3-dibenzylbutyrolactone derivatives into customary cosmetic and/or dermatological preparations (paragraph 0038). The 2,3-dibenzylbutyrolactone derivatives are taught to be useful for the treatment of skin aging symptoms, inflammatory skin conditions, unclean skin and acne (paragraphs 0299-0304). Stab et al. teaches that the concentration of the 2,3-dibenzylbutyrolactone derivatives ranges from 0.001% to 10%, which overlaps with the amounts in claims 21-23, 32 (paragraph 0033).

Stab et al. does not teach that the 2,3-dibenzylbutyrolactone derivatives are in combination with licochalcone A.

Max et al. teach cosmetic or dermatological preparations that contain licochalcone A for the treatment of postinflammatory skin conditions and contributes to a more even pigmentation of the skin (paragraphs 0019-0020). It is also taught that licochalcone A is useful for treating skin aging and the harmful effects of ultraviolet radiation on the skin (paragraph 0024). Max et al. teach concentrations of licochalcone A in the composition to range from 0.0001 to 5% by weight which overlaps with that in claims 24-26 (paragraph 0025). Max et al. teaches that polyols can be included in the composition in amounts ranging from 0.001 to 10% by weight, which overlaps with that in claims 28-30 (paragraph 0027). Max et al. teaches that the licochalcone A of the invention is a constituent of vegetable extracts, in particular *radix glycyrrhizae inflatae* (paragraphs 0028, 0032). Max et al. teach compositions that include licochalcone A and glycerin (meeting the limitation of the elected species of polyol) in amounts that overlap with those claimed in the present invention (see Examples 1-7, 9-13, 15-19).

Tom Dieck et al. teach the use of licochalcone A in cosmetic and dermatological preparations for the treatment of inflamed skin conditions and/or skin protection in dry skin (paragraphs 0002, 0032, 0044). Tom Dieck et al. teach that carriers are used in the cosmetic and dermatological formulations (paragraph 0107).

Accordingly, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows

logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980). One would be motivated to combine the teachings of Stab et al., which teach cosmetic and dermatological formulations comprising 2,3-dibenzylbutyrolactone derivatives, including the elected species of arctiin, for the treatment of skin aging symptoms, inflammatory skin conditions, unclean skin and acne, with the teachings of Max et al. and Tom Dieck et al. which teach cosmetic and dermatological formulations comprised of licochalcone A for the treatment of skin conditions for treating skin aging and the harmful effects of ultraviolet radiation on the skin and treatment of inflamed skin conditions and/or skin protection in dry skin, (which meet the method limitations in claims 39-44) because the 2,3-dibenzylbutyrolactone derivatives and licochalcone are used in cosmetic and dermatological preparations.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

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